IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, v. RAYMOND KRAYNAK, Defendant.	No. 4:17-CR-00403 (Chief Judge Brann)

MEMORANDUM OPINION

AUGUST 8, 2022

I. BACKGROUND

In 2017, Raymond Kraynak was indicted on twelve counts of unlawfully distributing and dispensing a controlled substance, in violation of 21 U.S.C. § 841(a)(1), five counts of unlawfully distributing and dispensing a controlled substance resulting in death, in violation of 21 U.S.C. § 841(a)(1), and two counts of maintaining a drug-involved premises, in violation of 21 U.S.C. § 856(a)(1).[1] After the completion of discovery, *Daubert* motions, and pretrial motions, trial commenced in this matter on September 7, 2021. Following approximately three weeks of trial, the Government rested its case in chief. Before Kraynak commenced his defense, however, he elected to enter into a plea agreement with the Government.

On September 23, 2021, Kraynak signed a written plea agreement, wherein he agreed to plead guilty to Counts One through Twelve of the indictment, and the

[1] Doc. 3.

Government agreed to dismiss the remaining charges.[2] That plea agreement is a Federal Rule of Criminal Procedure 11(c)(1)(C) agreement and, in the agreement, the parties agreed to a term of 15 years' imprisonment.[3] That same day, the Court conducted a thorough plea colloquy, accepted the guilty plea, and adjudged Kraynak guilty of those offenses.[4] On February 23, 2022, the Court notified the parties that it would accept the Rule 11(c)(1)(C) agreement and the term of imprisonment to which the parties had agreed.[5]

A presentence report was prepared, and Kraynak filed objections to that report.[6] In light of that report and the accompanying objections, on February 16, 2022, this Court scheduled a sentencing hearing that was set to occur on March 4, 2022.[7] Two days later, on February 18, 2022, Kraynak hand delivered to the Clerk's Office a *pro se* motion to withdraw his guilty plea.[8]

Based on that motion, the Court converted the sentencing hearing into a preliminary hearing on Kraynak's motion and, following the hearing, granted a motion to withdraw that was filed by Trial Counsel, Assistant Federal Public Defenders Thomas A. Thornton and Gerald A. Lord (collectively "Prior Counsel"),

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2 Doc. 216.
3 *Id.* at 10.
4 Doc. 219.
5 Doc. 234.
6 Docs. 228, 229.
7 Doc. 231.
8 Doc. 233.

and appointed a new attorney to represent Kraynak, Stephanie Cesare, Esq. ("Counsel").[9]

Counsel then filed a formal motion to withdraw the guilty plea.[10] In that motion, Kraynak argues—through Counsel—that he is actually innocent of the crimes to which he pled guilty, as he had a valid doctor-patient relationship with the victims identified in Counts One through Twelve, and the controlled substances that he prescribed to those victims had a logical connection to their underlying conditions or symptoms.[11] He further asserts that any licensing board issues are irrelevant to his guilt, reference to Pennsylvania's Medical Practice Act is improper, and the shortcomings listed by the Government in Paragraph 20 of the Indictment do not establish that Kraynak engaged in drug trafficking.[12]

Kraynak further asserts that he received ineffective assistance of counsel because Prior Counsel failed to obtain a forensic pathologist to testify as an expert witness at trial, was late in offering to the Government a summary of Carol A. Warfield, M.D.'s expert testimony and in obtaining an expert report from her, and was late in procuring the proposed expert testimony of Susan M. Skolly-Danziger, Pharm.D.[13] Prior Counsel also allegedly promised Kraynak that he could get out of prison early because of certain alternative dispositions, although Kraynak has not

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9 Docs. 241, 242.
10 Doc. 249.
11 Doc. 250 at 3-4.
12 *Id.* at 4-5.
13 *Id.* at 6-8.

explicated which programs those are.[14] Kraynak asserts that he later learned through his own research that he would be ineligible for those alternative dispositions.[15] Kraynak asserts that he was given the plea agreement only one hour prior to the change of plea hearing and "did not have a chance to reflect on the plea agreement or review it in any kind of detail."[16] Lastly, Kraynak contends that the Government would not be prejudiced if the Court were to grant his motion, as sentencing has not yet occurred and all evidence is still available to the Government.[17]

Kraynak later filed a supplemental motion to withdraw his guilty plea[18] based upon the United States Supreme Court's recent decision in *Ruan v. United States*.[19] Dr. Kraynak asserts that the *Ruan* case is similar to his and, here, the Government failed to prove at trial that he intended to prescribe controlled substances outside the usual course of professional practice and not for a legitimate medical purpose.[20]

On August 3, 2022, the Court conducted a hearing on Kraynak's motions to withdraw his guilty plea and received testimony from Kraynak, Kraynak's son—also named Raymond Kraynak—and Prior Counsel. At the conclusion of the hearing, that Court orally denied Kraynak's motion to withdraw his guilty plea. In

14 *Id.* at 9-10.
15 *Id.* at 10.
16 *Id.*
17 *Id.* at 11-12.
18 Doc. 253.
19 142 S. Ct. 2370 (2022).
20 Doc. 254.

accordance with that oral ruling, and for the reasons set forth below, the Court will deny Kraynak's motions to withdraw his guilty plea.

II. DISCUSSION

The United States Court of Appeals for the Third Circuit has repeatedly emphasized that "[o]nce accepted, a guilty plea may not automatically be withdrawn at the defendant's whim."[21] District courts nevertheless possess broad discretion to grant such motions, and "a defendant may withdraw a plea of guilty before sentencing if he 'can show a fair and just reason for requesting the withdrawal.'"[22] "A shift in defense tactics, a change of mind, or the fear of punishment are not adequate reasons to impose on the government the expense, difficulty, and risk of trying a defendant who has already acknowledged his guilt by pleading guilty."[23] "To determine if there has been [a showing of fair and just reasons to withdraw the plea], a district court must consider three factors (1) whether the defendant asserts his innocence; (2) the strength of the defendant's reasons for withdrawing the plea; and (3) whether the government would be prejudiced by the withdrawal."[24] "The burden of demonstrating those factors is substantial and falls on the defendant."[25]

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21 *United States v. James*, 928 F.3d 247, 253 (3d Cir. 2019).
22 *Id.* (quoting Fed. R. Crim. P. 11(d)(2)(B)).
23 *United States v. Jones*, 336 F.3d 245, 252 (3d Cir. 2003).
24 *James*, 928 F.3d at 253 (alterations and internal quotation marks omitted).
25 *Id.* (brackets and internal quotation marks omitted).

A. Whether Kraynak Asserts his Innocence

As to the first factor, whether Kraynak asserts his innocence, the Third Circuit has held that "[b]ald assertions of innocence are insufficient to permit a defendant to withdraw his guilty plea" and "[a]ssertions of innocence must be buttressed by facts in the record that support a claimed defense."[26] "Once a defendant has pleaded guilty, he must then not only reassert innocence, but give sufficient reasons to explain why contradictory positions were taken before the district court and why permission should be given to withdraw the guilty plea and reclaim the right to trial."[27] "[T]he defendant's burden is to credibly assert his legal innocence: that is, to present evidence that (1) has the quality or power of inspiring belief, and (2) tends to defeat the elements in the government's *prima facie* case or to make out a successful affirmative defense."[28] "[L]egal innocence alone can support withdrawal of a guilty plea."[29]

To establish that Kraynak unlawfully distributed and dispensed a controlled substance, in violation of 21 U.S.C. § 841(a)(1) and (b)(1)(C),

> the Government must prove four things: (1) that Kraynak distributed a mixture or substance containing a controlled substance; (2) that he distributed the controlled substance outside the usual course of professional practice and not for a legitimate medical purpose; (3) that he distributed the controlled substance while knowing or intending that the distribution was outside the usual course of professional practice

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[26] *Jones*, 336 F.3d at 252.
[27] *Id.* (internal quotation marks omitted).
[28] *James*, 928 F.3d at 255.
[29] *Id.* at 253.

> and not for a legitimate medical purpose; and (4) that the controlled substance was the substance identified in the indictment.[30]

This comports with the Supreme Court's recent conclusion in *Ruan* that "the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so."[31]

In this case there is no dispute that Kraynak prescribed the identified controlled substances to the identified patients during the identified timeframes, and, in any event, the evidence produced at trial plainly establishes that those two elements were met. Therefore, the only dispute as to Kraynak's guilt is whether he knowingly or intentionally issued the controlled substances outside the usual course of professional practice and not for a legitimate medical purpose.

1. Whether the Prescriptions Were Outside the Usual Course of Professional Practice and not for a Legitimate Medical Purpose

Although contested by Kraynak, the evidence overwhelming supports the conclusion that Kraynak's prescribing habits as to each of the identified victims was outside the usual course of professional practice and not for a legitimate medical purpose.

The Government's expert witness, Stephen Thomas, M.D., testified convincingly at trial that several steps must be taken by doctors when evaluating

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[30] *United States v. Kraynak*, 553 F. Supp. 3d 245, 251 (M.D. Pa. 2021).
[31] *Ruan*, 142 S. Ct. at 2375.

patients and prescribing controlled substances to those patients. First, every time a doctor meets with his or her patient, the doctor must do some, but not necessarily all, of the following: take the patient's history; conduct a physical examination of the patient; perform diagnostic tests, including potentially blood work, x-rays, MRIs, or CT scans; and finally, diagnose the patient to determine the proper course of treatment.[32] Dr. Thomas opined that a doctor cannot know the result of any particular treatment without doing at least some of those steps every time he meets with his patient.[33]

Dr. Thomas also testified that the Centers for Disease Control and Prevention recognized in 2011 that the United States was experiencing an opioid epidemic and, as a result, doctors began to "treat everybody as if they could potentially have a problem" with opioid addiction.[34] Consequently, when prescribing opioids, doctors must: (1) diagnose the patient; (2) assess the patient psychologically for any mental health disorders; (3) obtain informed consent from the patient; (4) assess the patient's pain and function to ensure that the medication is improving their functional abilities; (5) reassess the impact of the drugs every time they are prescribed; and (6) document the results of the prescription(s).[35] Doctors should also conduct a drug screen of the patient the first time they present to the doctor and

[32] Doc. 243 at 30-32.
[33] *Id.* at 33.
[34] *Id.* at 46.
[35] *Id.* at 46-48.

should conduct further follow-ups to ensure that the patient is taking the prescribed medication and not taking anything that was not prescribed.[36]

Importantly, Dr. Thomas also testified persuasively that "[t]he medical record is not optional."[37] Medical records are what permit doctors to track information, compare a patient's current condition to her prior condition, permit other doctors to see the patient's history, and allow a doctor to see how frequently he is prescribing a medicine to the patient and whether the patient is working toward her treatment goals.[38] Dr. Thomas also observed that "[t]he medical record is necessary because in every guideline regarding the control of controlled substances, the need for documentation is mentioned repeatedly."[39] He emphasized that such records are the only way that doctors "can objectively state that we are practicing medicine for the benefit of the patient and that we are doing so for a medically-legitimate purpose in the usual course of professional practice."[40] As Dr. Thomas stated in his expert report, "[t]he medical record distinguishes the practice of medicine from drug dealing. Absent medical documentation, in my opinion, the dispensing of controlled substances in type and amounts requested by patients because patients report satisfaction with the drugs is no different than any other form of drug dealing."[41]

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36 *Id.* at 48-49.
37 *Id.* at 54.
38 *Id.* at 54-55.
39 *Id.* at 55.
40 *Id.* at 55-56.
41 Doc. 60 at 5.

This comports with the model policy promulgated by the Federation of State Medical Boards which states that opioid prescriptions are only issued for a legitimate medical purpose if, among other things, there is careful follow-up monitoring of the patient and everything is "appropriately documented;"[42] that model policy contains a separate section that details what documentation should be contained in the patient's medical record.[43] Dr. Thomas emphasized that proper medical records are "not optional" and "in the absence of documenting history, physical examination, diagnostic studies, a medical decision-making and planning, there is no medical work done. And in the absence of medical work, it's not the practice of medicine. And if it's not the practice of medicine, it's not for a medically-legitimate purpose in the usual course of professional practice."[44]

Finally, Dr. Thomas discussed certain combinations of controlled substances that are potentially dangerous. He noted that benzodiazepines—which alone are fairly innocuous—are present in approximately 30% of fatal opioid overdoses and increase risk of fatal opioid overdose by 1,500 percent.[45] Dr. Thomas also discussed "trinity prescribing," which is the prescription of an opioid, benzodiazepine, and Soma, which is "known by physicians, pharmacists, and drug addicts as being drugs of choice among the potential abusers of the drug;" medical literature warns against

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42 Doc. 243 at 67; *see id.* at 63-67.
43 *Id.* at 68.
44 *Id.* at 68-69.
45 *Id.* at 43-44.

this prescribing practice due to its dangers, and Dr. Thomas explained that "trinity prescribing rarely can be justified chronically."[46]

Dr. Thomas then related these specific requirements and concerns to the victims identified in Counts One through Twelve of the Indictment.

Count One alleges the distribution of hydrocodone to R.C. from approximately December 21, 2012, through May 2, 2015.[47] R.C.'s medical records were stunning incomplete, with one short notation contained in the record on October 27, 2005, and no subsequent records at all during the nearly ten years that Kraynak treated her.[48] As Dr. Thomas explained, given that nothing in the record indicated any pain, any treatment plan, or any medical progress, so too did nothing in the record justify the prescription of opioids, as "there's a decade of silence. That's not the practice of medicine."[49]

Count Two alleges the distribution of oxycodone to F.H. from approximately December 21, 2012, to July 31, 2014.[50] F.H.'s blank intake form indicates—according to Dr. Thomas—that no physical examination was conducted.[51] Moreover, an August 23, 2010 report from Geisinger hospital showed that F.H. had previous addiction issues and three DUI convictions, all of which, according to Dr.

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46 *Id.* at 44.
47 Doc. 3 at 15-16.
48 Doc. 244 at 60-61.
49 *Id.* at 61-62.
50 Doc. 3 at 15-16.
51 Doc. 244 at 27-28.

Thomas, demonstrates that she was an addict and at great risk of drug abuse.[52] Importantly, F.H. had oxygen saturation issues and was obese, which would be dangerous on their own, but would be very dangerous when combined with an opioid that causes respiratory depression.[53] Despite this danger, and despite there being no prior indications of any pain other than knee pain from twisting her knee, Kraynak prescribed oxycodone to F.H. for osteoarthritis.[54] Dr. Thomas opined that the prescriptions were not for a legitimate medical purpose—they were dangerous, there was no monitoring of the drugs, and nothing showed that the drugs were working to ease any alleged pain.[55]

Count Three alleges the distribution of oxycodone to D.H. from approximately June 2013 to February 17, 2015.[56] Despite lengthy treatment from Kraynak, D.H. continued to have high pain levels, which indicated to Dr. Thomas that the opioids were providing no benefit to D.H.[57] Notably, she was prescribed oxycontin and directed to take one pill every 3 to 4 hours, even though that drug is long-acting and is designed to be used twice per day.[58] Dr. Thomas testified that this was inappropriate and would lead to a "stacking" effect and toxic doses.[59] D.H. was

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52 *Id.* at 29-30.
53 *Id.* at 33-34.
54 *Id.* at 34-35.
55 *Id.* at 35.
56 Doc. 3 at 15-16.
57 Doc. 244 at 76-77.
58 *Id.*
59 *Id.*

later admitted to the hospital for respiratory failure, heart failure, and asthma, all of which created a dangerous combination that should have led to hesitation in prescribing opioids, since her body would struggle to get oxygen to the lungs, and would struggle to get blood to the lungs to pick up that oxygen.[60]

Dr. Thomas testified that, when individuals are experiencing heart failure, they should be given less oxycodone because the body cannot handle a high quantity of drugs.[61] Despite these issues, there was no change in prescribing conduct from Kraynak; as Dr. Thomas summarized, "do we get demonstrable benefit to the patient? No. Demonstrable risk to the patient? Yes. Danger to the patient? Yes."[62]

Count Four alleges the distribution of oxycodone to A.K. from approximately December 21, 2012, to October 24, 2013.[63] A urine screen conducted on November 20, 2011, was negative for oxycodone, but positive for hydrocodone, despite the fact that Kraynak was prescribing oxycodone to A.K.[64] Despite this red flag, there is no indication that Kraynak addressed this issue with A.K. Furthermore, Kraynak treated A.K. for knee pain but, according to Dr. Thomas, such pain is relieved by sitting or lying down or by using a brace, and, therefore, opioids are rarely appropriate to treat this condition.[65] The record further showed a two-month gap between A.K.'s final

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60 *Id.* at 78-80.
61 *Id.* at 79.
62 *Id.* at 81.
63 Doc. 3 at 15-16.
64 Doc. 244 at 68-69.
65 *Id.* at 69-70.

prescription refills, which created an elevated risk of overdose due to lowered tolerance as a result of abstinence, but Kraynak nevertheless prescribed the same quantities of controlled substances to A.K.[66]

Count Five alleges the distribution of hydrocodone to M.L. from approximately December 21, 2012, to October 15, 2014.[67] In July 2010, M.L.'s urine drug screen came back positive for drugs that Kraynak had not prescribed, so M.L. was sent a "boot letter" removing her from Kraynak's practice.[68] Nevertheless, by July 2013 M.L. returned as a patient. There was no explanation in her medical record as to why she was readmitted, no reevaluation, and nothing to show that Kraynak did anything to address the prior issues that led to M.L. being booted from the practice in the first place.[69] She was also prescribed Xanax and Restoril, which perform the same function and, as Dr. Thomas testified, the combination is not more effective but, rather, is more toxic to the patient.[70]

Count Six alleges the distribution of oxycodone to C.S. from approximately December 21, 2012, to April 29, 2014.[71] At her initial intake, C.S. was being treated for gastrointestinal pain, which Dr. Thomas testified should not be treated with opioids since opioids actually cause gastrointestinal issues.[72] Three months later,

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66 *Id.* at 71-73.
67 Doc. 3 at 15-17.
68 Doc. 244 at 85-86.
69 *Id.* at 86-88.
70 *Id.* at 88.
71 Doc. 3 at 15-17.
72 Doc. 244 at 91.

C.S.'s pain had changed to a "history" of back pain, without explanation and Kraynak issued a trinity prescription, which has no basis for treating back pain.[73] Notably, a health insurance company wrote to Kraynak multiple times regarding the quantity and duration of prescriptions for carisoprodol, which exceeded the maximum allowable doses and durations, but Kraynak nevertheless continued to prescribe carisoprodol.[74]

During this time, C.S. continuously received prescription refills long before she should have run out of her medication if the medications were taken as directed.[75] Importantly, on April 22, 2014, C.S. was prescribed 120 pills of Soma, 30 pills of Ambien, 30 pills of valium, and 150 pills of oxycodone 30mg and, according to Dr. Thomas, nothing could justify this type and combination of prescriptions.[76] Nevertheless, she was then issued an identical prescription for those massive quantities of drugs only 7 days later, long before those medications should have been finished.[77] Dr. Thomas opined that "medically, there can be no rationale" for Kraynak's prescription behavior.[78]

In addition to this abusive prescription practice, the medical records that Kraynak kept were again deficient, with Dr. Thomas explaining "[w]e see an

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[73] *Id.* at 91-92.
[74] *Id.* at 92-96.
[75] *Id.* at 96-99.
[76] *Id.* at 99-100.
[77] *Id.* at 99.
[78] *Id.* at 100.

absence of documentation, no observable benefit, no clinical reasoning, no documentation of why . . . Kraynak was deciding to do what he did. And therefore, it is not for a medically-legitimate purpose in the usual course of professional practice."[79]

Count Seven alleges the distribution of oxycodone to D.B. from approximately January 2014 to October 5, 2014.[80] D.B.'s initial physical examination form was blank which, in Dr. Thomas' opinion, is "consistent with no physical examination being performed" or, at the very least, none having been recorded.[81] Dr. Thomas further testified that there was no supporting documentation to justify the prescription of hydrocodone, oxycodone, or tramadol.[82] The absence of documentation means, in Dr. Thomas' opinion, that the prescriptions were not for a "medically-legitimate purpose in the usual course of professional practice."[83]

Count Eight alleges the distribution of oxycodone to W.E. from approximately December 21, 2012, to December 14, 2014.[84] Records showed that Kraynak believed that W.E. was selling her medications, but he did not perform a pill count, despite a pill count being "the only way that you can check that part of the patient's behavior."[85] Kraynak's records also showed that, on December 29,

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79 *Id.* at 101.
80 Doc. 3 at 15-17.
81 Doc. 243 at 109.
82 *Id.* at 110-12.
83 *Id.* at 112.
84 Doc. 3 at 15-17.
85 Doc. 243 at 117-18.

2011, W.E. was treated at a hospital after an attempted suicide and was diagnosed with benzodiazepine and opioid dependence—Dr. Thomas opined that this shows that W.E. was an addict and at a greater risk from opioids.[86] On January 11, 2012, a psychologist recommended that Kraynak not restart Xanax or any other potentially addictive medication since W.E. must achieve sobriety, although this recommendation was ignored.[87] Kraynak later noted a history of drug abuse but continued to prescribe oxycodone to W.E., and prescribed oxycodone for a skull fracture that should have healed since it had occurred seven months prior, meaning that oxycodone would be unnecessary as any pain would have abated.[88]

Count Nine alleges the distribution of oxycodone to F.G. from approximately December 21, 2012, to February 10, 2013.[89] F.G. suffered from sleep apnea, which Dr. Thomas opined was a serious warning sign that opioids should not be prescribed because of an increased risk of death associated with that disorder.[90] F.G. also fell asleep at the wheel when driving, which was an additional warning sign because the combination of pills that Kraynak had prescribed to F.G. may cause drowsiness.[91] Another physician had given F.G. Aleve to treat his pain, and F.G. reported that his pain improved with this relatively innocuous pain reliever.[92] Nevertheless, Kraynak

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86 *Id.* at 120-22.
87 *Id.* at 123-24.
88 *Id.* at 128, 134-35.
89 Doc. 3 at 15-17.
90 Doc. 243 at 140-41.
91 *Id.* at 142-43.
92 *Id.* at 140.

prescribed F.G. opioids and, importantly, also prescribed high quantities of opioids ahead of schedule, before F.G. should have run out of his previous prescription.[93]

At one point, F.G. was prescribed oxycodone five days after having a previous prescription filled, which means that he would need to have taken 33 oxycodone pills per day to have required a new prescription, when he should have taken 8 pills per day at most.[94] This was a significant red flag. Many prescriptions were issued without explanation and with, in Dr. Thomas' opinion, "[n]o medical decision-making" involved.[95] The absence of any documentation to support the prescriptions issued, along with the excessive medications prescribed meant, in Dr. Thomas' opinion, that the prescriptions were not for legitimate medical purpose.[96]

Count Ten alleges the distribution of oxycodone to T.M. from approximately December 21, 2012, to April 28, 2014.[97] Although the records that Kraynak kept for T.M. were, as Dr. Thomas described, "woefully inadequate,"[98] those records revealed that a urine drug screen was positive for marijuana, which was illegal, but Kraynak never followed up on this.[99] T.M. was later admitted to the hospital for syncope and vertigo, and then again for a change in mental status, all of which was

93 *Id.* at 145-48.
94 *Id.* at 146-47.
95 *Id.* at 148.
96 *Id.* at 148-51.
97 Doc. 3 at 15-17.
98 Doc. 244 at 37.
99 *Id.* at 38.

likely tied to the prescriptions that she was issued by Kraynak.[100] The admitting hospital reduced her oxycodone prescription from 30mg to 10mg and advised Kraynak to stop prescribing 30 mg of oxycodone.[101] Nevertheless, Kraynak continued prescribing 30 mg of oxycodone, Xanax, and many other medications, including trinity prescribing.[102] Dr. Thomas opined this prescribing was dangerous and not for a legitimate medical purpose.[103]

Count Eleven alleges the distribution of fentanyl to J.S. from approximately January 2013 to July 6, 2016.[104] Notes from Geisinger hospital stated that J.S. may have Munchausen syndrome—a disorder where individuals seek treatment for conditions they do not have—which is a warning to a physician regarding the veracity of a patient's self-reported symptoms.[105] J.S. had multiple hospitalizations for left hand and arm abscesses and infections, which is common in intravenous drug abusers.[106] Pictures of her arms demonstrate infections that clearly originated from an injection site, as well as track marks. Dr. Thomas testified that this is plainly indicative of intravenous drug abuse and is something that Kraynak should have spotted.[107] The hospital that treated J.S. also noted that she was likely abusing

[100] *Id.* at 38-40.
[101] *Id.* at 40.
[102] *Id.* at 41-42.
[103] *Id.* at 42.
[104] Doc. 3 at 15-17.
[105] Doc. 244 at 43-44.
[106] *Id.* at 43-45.
[107] *Id.* at 45-48.

intravenous drugs, had history of opioid and ethanol abuse, and diagnosed her as opioid dependent.[108] Kraynak was involved in the treatment of those infections and, thus, knew that all of this was happening.

Despite these warning signs of drug abuse, Kraynak prescribed J.S. three separate opioids.[109] During this time, Kraynak made no notes in J.S.'s medical file that assessed her condition, function, or responses to medication.[110] Dr. Thomas opined that these prescriptions were not legitimate, as there was no explanation for the treatment decisions and, more importantly, there was no evidence of pain, but significant evidence of drug abuse.[111] Dr. Thomas opined that these prescriptions put J.S. at risk and were "not tangentially" related to any medical treatment.[112]

Count Twelve alleges the distribution of oxycodone to R.W. from approximately February 2013 to September 15, 2016.[113] Kraynak prescribed 15mg of oxycodone, with instructions that R.W. take two pills every two to three hours; Dr. Thomas opined that this was bad prescribing and heavy dosing, particularly since the peak effect of oxycodone occurs after two hours, at the same time that R.W. would be taking more oxycodone.[114] Kraynak also prescribed a benzodiazepine,

[108] *Id.* at 50.
[109] *Id.* at 51-52.
[110] *Id.* at 50-51.
[111] *Id.* at 55.
[112] *Id.*
[113] Doc. 3 at 15-17.
[114] Doc. 244 at 8-9.

which further increased the risk of an overdose.[115] Despite being prescribed these massive doses of controlled substances, R.W. reported no pain relief, indicating that the opioids were not working and should be discontinued.[116] Importantly, Kraynak conducted a pill count on May 20, 2014 which showed that R.W. had run out of the 250 oxycodone pills that he had been prescribed ten days previously—meaning that he took at least 25 pills per day—and R.W. had run out of diazepam.[117] This indicates either abuse or diversion.[118] Despite this warning flag, Kraynak prescribed an additional 250 oxycodone pills on the day of the pill count.[119]

R.W. was later hospitalized for psychosis and delirium from oxycodone and valium use, which Dr. Thomas opined is an "unacceptable side effect."[120] Geisinger hospital recommended that Kraynak lower the oxycodone doses and stop prescribing valium, but Kraynak nevertheless continued prescribing both at the same dose.[121] Kraynak also issued a trinity prescription to R.W., and Dr. Thomas opined that Kraynak was prescribing "notably toxic" levels of controlled substances.[122] Other events that should have presented major red flags to Kraynak is the fact that in early 2016 R.W. presented to the emergency room and requested narcotics, even though

[115] *Id.* at 9-10.
[116] *Id.* at 10.
[117] *Id.* at 13-14.
[118] *Id.* at 14-15.
[119] *Id.* at 26.
[120] *Id.* at 15-17.
[121] *Id.*
[122] *Id.* at 23-25.

he should only have received narcotics from Kraynak, and Kraynak received a letter from a pharmacy manager asking Kraynak to wean R.W. from opioids.[123]

Finally, despite the importance of accurate record keeping and detailed patient files, Dr. Thomas testified that Kraynak's records as a whole "were a mess,"[124] and were "the worst" that Dr. Thomas had seen in hundreds of cases that he had worked on.[125] The records were mixed together, not in a dated order, and were deficient in the manner in which they described patient history, physical examinations, and medical decision-making.[126] The medical records created by Kraynak were so incomplete that Dr. Thomas was unable "to understand . . . Kraynak's clinical decision-making regarding his controlled substance prescribing."[127] The evidence of Kraynak's abusive prescription habits, along with the massive deficiencies in the patient records, strongly supports the conclusion that Kraynak's prescriptions to the victims identified in Counts One through Twelve of the indictment were not issued in the usual course of professional practice or with a legitimate medical purpose.

Dr. Thomas' review of the medical records and the absence of examinations or other procedures that would have rendered acceptable the prescription of controlled substances was confirmed by patient testimony. Several patients, including Kathleen G., Rachel W., Candice A., Jennifer D., Gail K., Elizabeth K.,

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[123] *Id.* at 18-21.
[124] Doc. 243 at 91.
[125] *Id.* at 91-92.
[126] *Id.* at 91-94.
[127] *Id.* at 93.

David B., and Dawn S. confirmed that they often had no physical examinations at all and/or had appointments that lasted fewer than five minutes.[128] Kerry A., a former employee of Kraynak's, confirmed that Kraynak would often see patients for only one to three minutes total.[129]

Kraynak also engaged in unwanted sexual contact with several patients, including Kathleen G., Rachel W., Candice A., and Elizabeth K., which brought his interactions with them outside of the doctor-patient relationship.[130] All of this information strongly demonstrates that the prescriptions that Kraynak issued to the victims identified in Counts One through Twelve were issued outside of the usual course of professional practice and without a legitimate medical purpose.

2. Whether the Evidence Established that Kraynak Acted Knowingly or Intentionally

Turning then to the question of whether Kraynak *knew or intended* for those prescriptions to be outside of the usual course of professional practice and without a legitimate medical purpose, the Court concludes that the evidence presented by the Government strongly demonstrates that the answer to that question is yes. Although Kraynak denies any such intent, the circumstantial evidence reveals otherwise.

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[128] Doc. 257 at 133-34, 187; Doc. 258 at 16; Doc. 259 at 72-73, 84, 155; Doc. 260 at 15; Doc. 261 at 67-68.

[129] Doc. 260 at 170, 204.

[130] Doc. 257 at 138-39, 197-98; Doc. 258 at 53-54; Doc. 260 at 19-20

As the Supreme Court stated in *Ruan*, "[t]he Government, of course, can prove knowledge of a lack of authorization through circumstantial evidence."[131] The Supreme Court noted that "the regulation defining the scope of a doctor's prescribing authority does so by reference to objective criteria such as 'legitimate medical purpose' and 'usual course' of 'professional practice'"[132] and emphasized that "'the more unreasonable' a defendant's 'asserted beliefs or misunderstandings are,' especially as measured against objective criteria, 'the more likely the jury will find that the Government has carried its burden of proving knowledge.'"[133]

Here, evidence that Kraynak's conduct violated objective medical standards—and that he knew that he was violating those standards—strongly indicates intent. First, as a result of a consent order into which Kraynak entered, he was required to take "a comprehensive, intensive course in the management of controlled substances" and, according to Dr. Thomas, that course provided "at least 30 hours of direct instruction on . . . the risk of unbridled controlled substances prescribing, about the risk of the combinations of drugs that would lead to intoxication, about the risk of the development of dependence, habituation, loss of control, and addiction, as well as how to monitor for the benefits."[134] The consent order that directed Kraynak to attend the intensive course in controlled substance

[131] 142 S. Ct. at 2382.
[132] *Id.* (quoting 21 C.F.R. § 1306.04(a)).
[133] *Id.* (quoting *Cheek v. United States*, 498 U.S. 192, 203-04 (1991)).
[134] Doc. 243 at 62.

management also provided that he admitted no wrongdoing, but found that he had departed from standards of acceptable medical practice in prescribing controlled substances. This demonstrates that Kraynak was well aware of the objective medical standards that should apply when issuing a controlled substance prescription, but nonetheless violated those standards.

Although Kraynak argues that references to the administrative licensing actions taken against him are immaterial, the Government's expert witness, Stephen Thomas, M.D., testified convincingly that accurate record keeping is primarily what distinguishes medical practice from drug dealing. Based on the administrative licensing actions and subsequent educational courses that Kraynak was required to take, it is evident that Kraynak knew that he was required to keep certain records but failed to do so. It is also evident that he was aware of the medical standards that apply when issuing opioid prescriptions, but intentionally violated those standards.

Other evidence likewise establishes that Kraynak knew he was violating objective medical standards in issuing prescriptions. Kraynak or his office was informed several times that patients were addicted to opioids. In that vein, Kathleen G. once informed Kraynak that she was addicted to opioids, but he continued prescribing opioids to her.[135] Jennifer D.'s sister called to tell Kraynak's office that Jennifer D. was an addict, but Kraynak continued to prescribe Jennifer D. controlled

[135] Doc. 257 at 136.

substances.[136] Anthony K., the husband of Elizabeth K., confronted Kraynak in person and told him Elizabeth K. was addicted to opioids and needed help, yet her opioid prescriptions continued unabated and, in fact, Kraynak then prescribed opioids to Anthony K., knowing that Anthony K. would give those opioids to his wife.[137] Dawn S. had informed Kraynak that the opioids he prescribed to her—which were intended to last for thirty days—would only last one week. Kraynak did nothing except make her appointments more frequent.

Other evidence also indicates that Kraynak knowingly violated objective medical standards. Rachel W. testified that she refused to show up for pill counts, yet she continued to receive opioid prescriptions.[138] Kraynak would frequently modify Candice A.'s prescriptions to permit her get early refills without asking why an early refill was necessary.[139] Yvonne G. failed a urine screen and continued to receive opioid prescriptions from Kraynak.[140] Kraynak treated David B. for drug addiction yet increased David B.'s drug dosage at David B.'s request without asking any questions; this dosage was so high that only one pharmacy would fill the prescription because the prescription provided "an overdose" quantity of narcotics.[141] This, of course, is in addition to the previously-discussed evidence that

[136] Doc. 259 at 136-39.
[137] Doc. 260 at 76-77.
[138] Doc. 257 at 191-92.
[139] Doc. 258 at 21-22.
[140] Doc. 258 at 316-18.
[141] Doc. 261 at 68-70.

demonstrates Kraynak frequently did not examine his patients, spent little time with them, and kept incredibly poor patient records.

Moreover, numerous pharmacists began to refuse to fill prescriptions for controlled substances that were issued by Kraynak, including pharmacists at Wal-Mart, Rite Aid, Burch Drug Store, CVS, Weis Markets Pharmacy, and Belski Community Pharmacy.[142] These pharmacists refused to fill prescriptions due to numerous red flags, including duplicate prescriptions, prescribing large quantities of opioids, patients traveling long distances to obtain prescriptions from Kraynak, prescribing the same medications to many patients, providing similar diagnoses to a broad spectrum of patients, prescribing combinations of drugs that presented a significant risk of death, patients often paying cash, and patients often "pharmacy shopping."[143] The fact that so many pharmacies and pharmacists were refusing to fill Kraynak's controlled substance prescriptions would have alerted him to the fact that the prescriptions he was issuing were unjustified and unjustifiable.

Finally, the Government presented prescription data that demonstrated that 94.38% of controlled substances that Kraynak prescribed were opioids and that, from 2014 to 2016, he was the top prescriber of oxycodone and hydrocodone in the state of Pennsylvania, while in 2017 he was the second highest prescriber in the

[142] Doc. 258 at 137-38, 140; Doc. 261 at 21-22, 109-10, 190-91; Doc. 262 at 8-9, 15, 37, 77, 136-38.

[143] Doc. 258 at 136-38; Doc. 261 at 14-18, 205-08; Doc. 262 at 39.

state.[144] This is particularly noteworthy because Kraynak did not serve a large urban community but, rather, served a small rural area with a relatively small population. In 2015, Kraynak prescribed more than 1,997,202 oxycodone or hydrocodone pills, and in 2016 that number was 1,880,223 pills, while in 2017 the number was 1,433,306 pills.[145] In 2015 and 2016, Kraynak alone prescribed more opioids than the whole of the Department of Veteran's Affairs hospitals in either Philadelphia, Pennsylvania, or Pittsburg, Pennsylvania.[146] These numbers support the conclusion that Kraynak knew and intended that his prescriptions were issued outside the usual course of his professional practice and without a legitimate medical purpose.

Kraynak's abusive prescription practice was summed up best by Dr. Thomas during the trial when he analyzed Kraynak's prescription practices. Dr. Thomas stated:

> [In] each instance, I have taken it from if I'm inside that practice and I know at the time what he [meaning Dr. Kraynak] knew when he knew it, can I make this judgment that it is not for a medically-legitimate purpose in the usual course of professional practice. This is not Monday morning quarterbacking. This is from sitting in the pocket. And he knew what was happening and he did it anyway. And that's what makes it not just a problem with the standard of care; that's what make[s] it[] not the practice of medicine. It's not in the patient's best interests, and he knew it wasn't. He endangered patients, and he knew it did.
>
> And that makes it not for a medically-legitimate purpose in the usual course of professional practice, and it cannot [be]. It cannot.[147]

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144 Doc. 266 at 141-46.
145 *Id.*
146 *Id.* at 142-44.
147 Doc. 244 at 101-02.

In sum, the evidence overwhelming established Kraynak's guilt for the crimes charged in Counts One through Twelve on the Indictment to which he pled guilty. He has not and cannot credibly assert his innocence. His protestations to the contrary are incredible, and Kraynak himself confirmed at the change of plea hearing that the evidence presented at trial established his guilt.[148] For the reasons set forth during the hearing on Kraynak's motion to withdraw his guilty plea, any contrary testimony offered by Kraynak at that hearing is not believable and is entitled to no weight.

B. Strength of Kraynak's Reasons to Withdraw the Plea

Turning then to the second factor—the strength of Kraynak's reasons for withdrawing his guilty plea—the Court likewise concludes that this factor weighs against granting Kraynak's motion to withdraw his guilty plea. The Third Circuit has held that a "court will permit a defendant to withdraw a guilty plea based on ineffective assistance of counsel only if (1) the defendant shows that his attorney's advice was under all the circumstances unreasonable under prevailing professional norms; and (2) the defendant shows that he suffered 'sufficient prejudice' from his counsel's errors."[149]

Viewing this case globally, Kraynak's assertion that he received ineffective assistance of counsel when Prior Counsel advised him to plead guilty strains credulity. Given the overwhelming evidence of guilt presented by the Government,

[148] Doc. 238 at 20.
[149] *James*, 928 F.3d at 258 (internal quotation marks omitted).

Prior Counsel's advice to plead guilty was eminently reasonable. Kraynak faced a high likelihood of being convicted of the crimes with which he was charged. Five of those charges carried a mandatory minimum sentence of 20 years' imprisonment, and the Sentencing Guidelines range had Kraynak been convicted of even one of those five counts would have been 360 months to life imprisonment. Prior Counsel was able to arrange a plea agreement that provided for 15 years' imprisonment, which was effective representation under the circumstances. Kraynak himself stated at the change of plea colloquy that he was satisfied with the legal representation that he had received from Prior Counsel.[150]

Furthermore, the three primary reasons that Kraynak provides to explain why he received ineffective assistance of counsel fail. First, Kraynak contends that he asked Prior Counsel to procure a forensic pathologist but they did not do so. He argues that, without such an expert, he could not rebut Dr. Thomas' assertion that, but for the prescriptions issued by Kraynak, the five patients charged in Counts Thirteen through Seventeen would not have died. However, Kraynak at the change of plea colloquy made no mention of any dissatisfaction with Prior Counsel's decision not to obtain such an expert and, to the contrary, Kraynak stated under oath that he was satisfied with his legal representation.

[150] Doc. 238 at 4-5.

Even if Kraynak was dissatisfied with the decision not to obtain a forensic pathologist, there is no evidence that Kraynak's expert witness, Carol A. Warfield, M.D., a professor and pain specialist at Harvard Medical School, could not adequately attempt to rebut Dr. Thomas' testimony—particularly since her expert report mirrored a defense that Prior Counsel was attempting to mount against those charges related to the victims' misuse of the drugs that Kraynak prescribed.[151] Dr. Warfield has the same medical qualifications as Dr. Thomas and therefore could logically also have testified as to the but-for cause of certain victims' deaths. Assistant Federal Public Defender Thomas Thornton testified at the hearing on Kraynak's motion to withdraw his guilty plea that Mr. Thornton planned to have Dr. Warfield counter Dr. Thomas' but-for opinion, and Mr. Thornton believed that this testimony was sufficient to properly counter Dr. Thomas' expert opinion.

Moreover, Dr. Warfield's opinion that Kraynak's prescriptions were not outside the usual course of professional practice and had a legitimate medical purpose would have directly attacked one of the elements necessary to prove the crime of distribution of a controlled substance causing death and, had Dr. Warfield undermined that element of the five offenses, Kraynak would have been acquitted of those charges regardless of whether the prescriptions that he issued were the but-for causes of the identified deaths. Therefore, there is no evidence of prejudice.

[151] Doc. 250-4 at 3.

Further emphasizing this lack of prejudice is Kraynak's statement at the hearing that Dr. Warfield's expert report was "outstanding" and that he never would have pled guilty had he read Dr. Warfield's expert report prior to the change of plea hearing. Having admitted under oath that he would have proceeded with trial had he simply read Dr. Warfield's expert opinion prior to pleading guilty—Kraynak acknowledged at the hearing that he had that report in his possession prior to pleading guilty—Kraynak cannot establish that Prior Counsel's failure to call a forensic pathologist prejudiced Kraynak by causing him to plead guilty.

Second, although Kraynak asserts that he was assured by Prior Counsel that he would be eligible for certain programs that would reduce his actual sentence below fifteen years—and he only subsequently learned through his own research that he would not be eligible for those programs—such an assertion is belied by the facts.[152] At the change of plea colloquy, Kraynak stated that no one had "promise[d] or offer[ed] [him] anything aside from the written plea agreement in order to get [him] to plead guilty before the Court."[153] This Court does not find credible Kraynak's self-serving and contradictory statements that attempt to rebut his sworn statement made during the change of plea hearing.

Most importantly, one of Kraynak's former attorneys, Assistant Federal Public Defender Gerald A. Lord, testified that he never promised, nor would he ever

[152] Additionally, Kraynak presented no evidence that he in fact does not qualify for any such programs.

[153] Doc. 238 at 19.

promise, that Kraynak would qualify for certain programs that would reduce Kraynak's sentence. Although Mr. Lord believed that Kraynak would almost certainly qualify for good time credit unless he got into trouble, and good time credits would reduce his total sentence to approximately 12 ½ years, Mr. Lord testified that he was concerned whether Kraynak would qualify for programs such as the First Step Act or the Residential Drug Abuse Treatment program because of the allegations that Kraynak caused the death of certain victims. Mr. Lord therefore felt that it was only *possible* that Kraynak could further reduce his sentence. Mr. Lord was clear that he "wouldn't have guaranteed anything." Mr. Thornton likewise confirmed that Mr. Lord mentioned certain programs from the Bureau of Prisons "that could *possibly* lessen" Kraynak's sentence. Mr. Thornton also informed Kraynak that they did not know whether he would qualify for those programs, and the only guarantee was that Kraynak could qualify for good time credit.

That testimony is persuasive, and the Court concludes that, although Prior Counsel mentioned the possibility that Kraynak could reduce his sentence to as little as perhaps five years' imprisonment through certain programs offered by the United States Bureau of Prisons, no promises were ever offered, and Prior Counsel was clear that Kraynak may have to serve the entirety of his sentence. This Court therefore cannot find either that Prior Counsel provided deficient advice, or that there was any resulting prejudice based on Prior Counsel's statements.

Third, Kraynak asserts that he had insufficient time to review the plea agreement and reflect on it in any meaningful way. However, during the change of plea colloquy Kraynak stated that Prior Counsel had "adequately explained the plea agreement to" him.[154] The Government summarized in detail the terms of plea agreement in open court, and Kraynak stated that the Government had accurately summarized the terms of the plea agreement as he understood them.[155] This undermines any assertion that Kraynak did not adequately understand the plea agreement or have sufficient time to review that agreement. Furthermore, Mr. Lord testified at Kraynak's hearing on his motion to withdraw the guilty plea that he was satisfied that Kraynak understood the plea agreement after Prior Counsel reviewed it with him word for word. Consequently, Kraynak again can demonstrate neither deficient advice nor prejudice.

To the extent that Kraynak may be asserting that he was pressured into accepting the plea agreement, the Third Circuit has held that any assertion that a plea was coerced or otherwise not entered into knowingly or voluntarily may be undermined when "statements [made] during the change-of-plea hearing indicate that his plea was indeed knowing, voluntary, and fully informed," such as statements that a defendant "reads and writes in English," "had an opportunity to have the documents in this case explained to him," and gave "affirmative responses when

[154] Doc. 238 at 14-15.
[155] *Id.* at 15-18.

asked if he was competent, if the plea agreement had been explained to him, and if he had had a full opportunity to make an informed decision."[156] That is the exact situation with which we are confronted here—this Court conducted a thorough plea colloquy wherein Kraynak affirmatively stated that he had not been coerced or pressured into pleading guilty, nor had he been promised anything other than what was contained in the plea agreement to get him to plead guilty. He reads and writes English, is a well-educated doctor, fully understood what he was doing and why he was doing it when he pled guilty, and stated that he had reviewed and understood the plea agreement. Accordingly, there is no indication that Kraynak's guilty plea was in any way coerced or otherwise involuntary.

Finally, Kraynak also asserts that one of his former attorneys, Mr. Lord, stated that Kraynak needed to answer yes to the questions asked of him during the change of plea hearing if he wished for the Court to accept his guilty plea. Mr. Lord testified, however, that he does not recall ever having said that Kraynak needed to say yes to all questions, although he would have advised Kraynak that Kraynak needed to affirm that he was guilty of the offenses to which he was pleading guilty. Mr. Lord testified that he never counseled Kraynak to lie, and that he ordinarily would advise his clients not to say they are guilty to an offense if they were innocent. The Court

[156] *James*, 928 F.3d at 258.

finds that Mr. Lord's testimony is credible, and finds that he never advised Dr. Kraynak to say yes to a question even if that answer was a lie.

In sum, Kraynak did not receive ineffective assistance of counsel. Given the weakness of Kraynak's reasons for withdrawing his guilty plea, this factor weighs against granting Kraynak's motion.

C. Whether the Government Would be Prejudiced by the Withdrawal

Finally, the Court turns to the third factor—prejudice to the Government. As an initial matter, this factor is of little importance given that the other two factors weigh against granting the motion, and the Third Circuit has held that where a defendant "failed to meaningfully reassert his innocence or provide a strong reason for withdrawing his plea, the Government was not required to show prejudice."[157] Nevertheless, this factor weighs heavily in favor of denying Kraynak's motion.

The Government spent a great deal of time and money preparing for trial. It then spent nearly three weeks presenting evidence—including days of expert testimony from an expert witness who charges $550 per hour—and it would need to again present this evidence if Kraynak were permitted to withdraw his guilty plea. Not only would this be expensive and time consuming, but some of the witnesses would be forced to testify a second time regarding traumatic experiences from their

[157] *Jones*, 336 F.3d at 255.

past. This is significant prejudice that weighs in favor of denying Kraynak's motion to withdraw his guilty plea.

Having examined all three factors that are relevant to whether to grant a defendant's motion to withdraw his guilty plea, the Court concludes that all three factors weigh against granting Kraynak's motion to withdraw his guilty plea. His motions to withdraw his plea of guilty will therefore be denied.

III. CONCLUSION

For the foregoing reasons, Kraynak's motions to withdraw his guilty pleas will be denied.

An appropriate Order follows.

BY THE COURT:

s/ Matthew W. Brann
Matthew W. Brann
Chief United States District Judge